LITE DEPALMA GREENBERG & AFANADOR

570 Broad Street / Suite 1201 / Newark, NJ 07102
973.623.3000 Main / 973.623.0858 Fax / litedepalma.com

Newark / Philadelphia

April 23, 2025

VIA EMAIL & ECF
Hon. Douglas E. Arpert, U.S.M.J. (Ret.)
Three Gateway Center
100 Mulberry Street, 15th Floor
Newark, New Jersey 07102

Re: ***U.S. ex rel. Silbersher v. Janssen Biotech Inc.***
Civil Action No. 19-12107 (MEF)(SDA)

Dear Judge Arpert:

Plaintiff-Relator Zachary Silbersher ("Relator") submits this response to Defendants' April 22, 2025 letter seeking yet another extension for their time to serve expert reports (ECF No. 398) ("Mot.")—even though Defendants have already received prior extensions to serve their expert reports to ten (10) months from the close of fact discovery (compared with Relator's two months). (ECF No. 335 & 431).

There are, unfortunately, several misstatements in Defendants' letter, beginning with their accusation that, as with "Defendants' prior attempts to negotiate with Relator, he has refused entirely . . . ." (Mot., 1) As Defendants know, Relator has routinely granted Defendants' many extension requests in the past, including Relator's prior agreements to postpone the depositions of Defendants' witnesses for similar personal reasons, and most recently on February 27 (ECF 426). This particular situation is different, and for good reason. It's important to understand the context of Defendants' latest request for another extension.

Defendants say that they have attempted to "resolve this issue by multiple emails between April 10 and April 21." That's not quite true. As Your Honor may note in the parties' correspondence attached as Exhibit A to the Motion, it was Relator who offered on April 10, without being specifically asked, to extend "any rebuttal report relating to Dr. Ratain" to one week after his deposition, and suggested a rescheduled deposition date on April 29 or 30.

It wasn't until April 19—this past Saturday over the Passover/Easter weekend—that Defendants *first* disclosed their intent to serve "more than one" report past the April 26 deadline that Your Honor set. (Mot., Ex. A, Smith April 19 e-mail at 12:22 pm)

Your Honor may note that in response, Relator did not object to the late service of more than one report outright, but he merely noted that Defendants in the past had tried improperly to "smuggle in" unrelated extensions of other reports; Relator therefore was objecting to late

service of additional reports "on the same improper basis." (*Id.*, Herrera April 19 email, at 7:04 pm, referring to issue described at *id.*, Herrera March 26 email at 9:58 am) In other words, Relator has always remained open to extend the time for Defendants to late serve expert reports if they were *reasonably* related to a postponed deposition—but not if the extensions were pretextual or without a reasonable basis (which happened before).

It wasn't until two days ago, on Monday, April 21, that Defendants first stated, purportedly for "the sake of transparency," that they would like to late serve *four* expert reports. Relator immediately responded, asking Defendants to "specify what 4 reports" Defendants would seek to serve late, as well as "the basis for [the] assertion" that they related to Dr. Ratain's report sufficient to merit another deadline extension. Indeed, Defendants have *already* deposed Dr. Ratain (in the underlying patent invalidation proceedings), and his report now is *extremely* thorough, so they already know what he will be opining, and why.

Defendants didn't respond to that email. Instead, yesterday during the deposition of Relator's manufacturing expert, Dr. Robert Femia, Defendants sent Relator a letter they intended to file at the end of the deposition, unless Relator agreed to their demands. During a 10-minute break in the deposition, at approximately 2:00 pm, Relator informed Defendants that the undersigned had difficulty reading the PDF letter (because the text was not rendering properly) and to please send a Word version that would be legible for Mr. Greenberg's review. Relator also informed Defendants that counsel would like to confer with Relator and co-counsel about Defendants' request, and asked Defendants' counsel to please explain why the three additional reports could not be served on time. Defendants' counsel responded that "it's all in the letter." Defendants did not provide any additional information, opting instead to precipitously file the Motion soon after Mr. Femia's deposition concluded.

The reason for Defendants' refusal to elucidate a reasonable basis to drag in three additional rebuttal reports that do not pertain to Dr. Ratain during what should have been good faith discussions with counsel, is because Defendants' vague arguments cannot withstand scrutiny.

Dr. Mark Ratain is Relator's oncology expert, whose opinion focuses on explaining why the claimed invention in the allegedly fraudulent patent (co-administering prednisone with abiraterone) was obvious when the patent application was filed, and explaining that Defendants had no reasonable basis to claim that coadministration increased the therapeutic efficacy of abiraterone (the active ingredient in Zytiga). Relator offered to extend any rebuttal report on any aspect of Dr. Ratain's opinion, as expressed in his expert report.

The other three reports that Defendants want to drag in do not rebut Dr. Ratain's opinion. One proposed report supposedly rebuts the opinion of Dr. David Hyman, who is Relator's expert opining on healthcare laws and regulations, including how Medicare, Medicaid, and Veterans' Health Administration data are created and reflect claims for payment to government healthcare

programs. Among other things, Dr. Hyman will opine on the importance of generic competition in government healthcare programs and pricing. There is no reason why a rebuttal to Dr. Hyman's report should be delayed because of the rescheduled deposition date for Dr. Ratain.

Similarly, Professor Shine Tu will opine on what a reasonable patent prosecutor would have understood her ethical obligations to the Patent Office to have required. On the flip side of the coin, Mr. Robert Bahr, a former Deputy Commissioner of Patents at the United States Patent and Trademark Office, will opine on the patent examination process at the Patent Office, including what the Patent Office would have expected inventors, patent prosecution attorneys, and other related applicant representatives to have disclosed during patent examination process. Defendants' rebuttals to either of these opinions do not reasonably rely upon Dr. Ratain's oncology opinion sufficient to justify yet another extension to serve Defendants' expert reports.

Defendants allude to supposedly late-produced data relating to Professor Tu's opinion in footnote 1 of the Motion. This is a red herring, and Defendants' characterization of this issue is not correct. Paragraph 67 of Professor Tu's 86-page, 286 paragraph report makes the point that commercial success arguments are rarely raised during the prosecution of pharmaceutical patents (about 1% of cases). He properly discloses the underlying facts and data he considered, explaining that he queried an analytical tool available at Lexis-Nexis at the following Website (wwwl.lexisnexisip.com/solutions/patent-prosecution/patentadvisor/.) to identify "all Orange Book listed patents from 2000 to 2023, which yielded a set of 7,133 patents." Professor Tu then searched for the term "commercial success" in the responses and found that a commercial success argument was used in about 75 of them. It's a rather discrete statement in an 86-page report, and the material facts and data were disclosed, including the exact website that Defendants could run the query for themselves.

In their Motion, Defendants claim that they have been hobbled in putting together a rebuttal report over the past 10 months, because they did not get a printout of Dr. Tu's queries (and although Defendants never previously asked for it, despite Relator's repeated offer to provide printouts of any sources that were publicly available on the Internet, upon Defendants' request). When finally requested, Relator provided the output the next business day. Of course, the query output includes mostly immaterial information, such as the names of the attorneys and patent examiners involved. This is yet another example of Defendants grasping at trivial matters to create a false narrative that they somehow have been hampered during expert discovery, and using these minor disputes as pretext to delay trial.

Your Honor may recall that Defendants have filed, and then withdrawn, several discovery motions taking issue with similarly trivial matters. For example, Defendants' primary complaints related to (a) missing pin-cites for a small number of citations out of hundreds; (b) Defendants' insistence on receiving printed copies of publicly-available documents for which Relator provided citations and hyperlinks; and (c) Defendants' demand for references that the experts

screened and disregarded as irrelevant in conducting background legal and medical research. *See generally* ECF 403 & 406.

Relator is now merely requesting Defendants to justify late serving additional rebuttal reports that they concede do not "directly" rebut Dr. Ratain's expert report. This is not an unreasonable request, given Defendants' history of delay. Defendants wrongly accuse Relator of not properly making disclosures in his expert reports/ but this is easily falsifiable. As Relator has stressed before, the Court does not need to take anyone's word on this: Relator provided the Court with a redline of the supplemental disclosures in ECF 403-1 & 404 to demonstrate the trivial nature of the additional information Defendants have chosen to repeatedly fight over, so the Court can see for itself. Defendants have simply leveraged Relator's willingness to compromise as an excuse to substantially delay their expert report deadline.

This case has been pending before this Court for five years—and it was originally filed under seal two years before that, in 2017. FED. R. CIV. P. 1 provides that the federal rules "should be construed, administered, and employed by the court" to "secure the just, speedy, and inexpensive determination of every action and proceeding." The Court should reject Defendants' incessant attempts to delay the proceedings, and to use the delay to gain additional unfair advantages over Relator.

The need to rein in Defendants' increasingly incessant attempts to delay trial should be viewed in context with how government healthcare programs are being affected by Defendants' litigation conduct. Based on the latest notice by the Acting Administrative Director of the Courts, the post-judgment interest rate in New Jersey is currently 7.5% as of January 1, 2025. At this rate, and based on the amount at stake in this litigation, every year that Defendants delay trial avoids $750 million per month of post-judgment interest that would be awarded to government healthcare programs. That is $62.5 million for each month, or over $2 million for each day, that Defendants are able to delay trial. Relator therefore respectfully requests Your Honor require Defendants to convincingly substantiate any further requests to delay the trial date in this case.

Respectfully,

/s/ Bruce D. Greenberg

Bruce D. Greenberg

BDG:emp

cc: All Counsel (via ECF)